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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,718	09/22/2003	R. Stephen Brown	14453	4655

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EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,718	BROWN ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-35 and 54-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 24, 25, 28-35 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Collins (EP 0044140).

With respect to claims 24 and 54, Bentsen discloses a system for detecting the presence of microorganisms. The system includes a vessel in which the microorganisms in the sample are incubated. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An excitation light source is provided for irradiating the biological molecule, and a detector is used to detect any subsequent fluorescence from the biological molecule. The detected fluorescence is indicative of the presence of microorganisms in the sample. This is disclosed in column 2, line 54 to column 3, line 22 and column 16, line 11 to column 19, line 18. Column 24, lines 6-9 and 47-57 indicate that a controller is provided for regulating the operation of the light source. Bentsen, however, does not expressly disclose the use of a partitioning element that allows partitioning of the biological molecule thereinto.

Collins discloses a method for carrying out a binding assay in which an enzyme selectively binds to a substrate to produce a detectable biological molecule. The biological molecule is characterized by solubility properties that are substantially different from those of the enzyme and substrate reactants. This is disclosed on page 3, lines 3-13. Page 5, line 22 to page 6, line 4 states that the biological molecules are separated from the treated reaction mixture using solvent partition procedures.

Bentsen and Collins are analogous art because they are from the same field of endeavor regarding enzyme detection through fluorescence.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen with partitioning solvent in order to detect fluorescence from the produced biological molecule. On page 3, line 28 to page 4, line 13, Collins indicates that solvent

partitioning techniques are widely applicable to binding assays similar to those described by Bentsen. The use of a partitioning element in the form of a solvent is desirable because it ensures that all detected emission light is produced by enzyme-substrate biological molecules, and not by peripheral cellular molecules. In this way, more accurate measurements regarding the amount of biological molecules (and thereby the amount of microorganisms) in the sample solution can be obtained.

With respect to claims 25 and 28, Bentsen and Collins disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Bentsen discloses in column 22, line 65 to column 23, line 5 and column 24, lines 7-9 and 47-57 that the apparatus is provided with control means for regulating the operation of the system, as well as control means for storing and outputting fluorescence data. A processor assembly (Figure 1:350) is provided for transmitting data electronically.

With respect to claims 29, 30 and 32, Bentsen and Collins disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. In addition, Bentsen discloses in column 17, lines 10-52 that the organism is *Escherichia coli*, and that the sample is selected from water, biological samples, food, and soil.

With respect to claims 31 and 33, Bentsen and Collins disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Bentsen additionally indicates in column 16, lines 22-59 that beta glucuronidases and beta galacotsidases are known in the art as

enzymes that are used in the detection of microorganisms. Column 3, lines 14-16 and column 16, lines 22-59 indicate that glucuronides and galactopyranosides are known in the art as acceptable substrates.

With respect to claims 34 and 35, Bentsen and Collins disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. As previously noted, Bentsen discloses in column 22, line 56 to column 23, line 5 that the system includes optical components (Figure 1:340) for monitoring fluorescence detection. Bentsen teaches that fluorogenic dyes are attached to the substrate, and incorporated into the biological molecule formed by the substrate-enzyme reaction. This is disclosed in column 10, lines 7-14.

2) Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Collins (EP 0044140) as applied to claim 24, and further in view of Lee (US 20030222012).

Bentsen and Collins disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of a removable cartridge in the vessel that is capable of containing the sample and the substrate. Bentsen and Collins do not disclose a removable cartridge containing a partitioning element.

Lee discloses a removable cartridge that comprises a mesoscale filter that is capable of partitioning cellular components in a sample. Detectable compounds are moved through the filter in an effort to remove undesirable cellular elements. The detectable compounds are then moved to a detector in order to verify their presence in the sample. This is disclosed in

paragraphs [0008], [0012], [0016]-[0018] and [0045]-[0048]. Paragraph [0069] specifically states that the device is configured as a cartridge for easy insertion and removal from a vessel, and paragraph [0071] indicates that the device is used to biological microorganisms.

Bentsen, Collins and Lee are analogous art because they are from the same field of endeavor regarding microorganism detection devices.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen and Collins with a removable cartridge for containing the sample and partitioning biological molecule products. In paragraph [0069], Lee indicates that removable cartridges are beneficial because they can easily be moved from one reaction vessel to the next. Removable cartridges are known in the art to be reusable and therefore cost effective. Lee indicates in paragraphs [0012] and [0016]-[0018] that removable cartridges that employ partitioning membranes are especially beneficial because they represent a means by which biological molecules can be separated from undesirable cellular compounds that would otherwise interfere with accurate detection procedures.

3) Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Collins (EP 0044140) as applied to claim 24, and further in view of either Ritts (US 20030228681), Wolfbeis (US 5238809) or Loeb (US 7096053).

Bentsen and Collins disclose the apparatus set forth in claim 55 as set forth in the 35 U.S.C. 103 rejection above. Collins discloses that the partitioning element is in the form of a solvent, rather than a polymer film.

Ritts discloses a system for detecting the presence of an organism having at least one enzyme in a sample. The enzyme is introduced into a first compartment and a barrier separates the first compartment from a second compartment. Substrates positioned within the first compartment react with the enzyme and produce a detectable species that is transported across the barrier. This is described in paragraphs [004]-[0007], [0058] and [0242]-[0244]. Paragraphs [0061], [0074] and [0218] state that the barrier is a hydrophobic PDMS film.

Wolfbeis discloses a system in which the catalytic activity of enzymes is measured through the detection of emitted fluorescence. A vessel is provided in which microorganisms and enzymes are provided. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An optical fiber probe is inserted into the vessel for detecting the presence of the biological molecule. This is disclosed in column 9, line 63 to column 10, line 66. Column 6, lines 42-50 indicate that a partitioning element (Figure 4:23) is placed over the optical fiber probe in order to separate desired biological molecules from other compounds in the sample solution.

Loeb discloses a system in which an enzyme is allowed to react with at least one substrate to form a detectable biological molecule. An optical fiber probe, an excitation light source, and a detector are used to determine fluorescence produced by the biological molecule. Furthermore, column 5, lines 28-64 indicate that a partitioning element (Figure 1:118) is placed over the optical fiber probe in order to separate desired biological molecules from other compounds in the sample

Bentsen, Collins, Ritts, Wolfbeis and Loeb are analogous art because they are from the same field of endeavor regarding detection devices.

At the time of the invention, it would have been obvious to separate the biological molecules in the system of Bentsen using a polymer film partitioning element as opposed to a solvent partitioning element. As evidenced by Ritts, Wolfbeis and Loeb, membrane partitioning elements are well known in the art as useful mechanisms by which to isolate desired compounds during detection. It would have been obvious to construct this film partitioning element from PDMS since PDMS is a material that is inexpensive and easily manufactured using known microfabrication techniques.

Response to Arguments

Applicant's arguments filed 30 March 2007 with respect to the 35 U.S.C. 103 rejections involving the combination of Bentsen and Wolfbeis have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Bentsen and Collins.

The Collins reference addresses the deficiencies of Bentsen and Wolfbeis by indicating that it is known in the art to provide a partitioning element capable of isolating a detectable biological molecule product when conducting a binding assay. Specifically, Wolfbeis discloses the use of a partitioning solvent capable of separating the biological molecule product from enzyme and substrate reactants in order to increase detection efficiency.

Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER